JUN 2 2 2004

510(k) Summary

Submitter: Edwards Lifesciences LLC
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Date Prepared: October 29, 2003

Trade Name: Edwards Lifesciences Research Medical Inc. Pediatric Venous Return Cannulae (abbreviated to ERMI Pediatric Venous Return Cannulae)

Common Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, or Tubing (21 CFR 870.4210)

Predicate Devices: Research Industries' Various Cardiovascular Devices

Research Medical, Inc. Fem-Flex Femoral Access Cannulation Kit

Terumo L-Series 1968 Type Pediatric Venous Catheters

Device Description: The ERMI Pediatric Venous Return Cannulae are used to access the vena cavae or femoral vein during cardiopulmonary bypass.

Indications for Use: The Research Medical Dual Drainage Venous Return Cannulae are indicated for venous cannulation so that extracorporeal circulation of venous blood to a heart-lung machine may be achieved for a duration $\leq$ 6 hours. Venous Cannulae in sizes 6 Fr. to 18 Fr. can be used in pediatric patient populations.

The Research Medical Duraflo Heparin Treated Dual Drainage Venous Return Cannulae are indicated for venous cannulation so that extracorporeal circulation of venous blood to a heart-lung machine may be achieved for a duration $\leq$ 6 hours. Venous Cannulae in sizes 6 Fr. to 18 Fr. can be used in pediatric patient populations. Extracorporeal circuit components with a Duraflo Treatment are indicated for use in cardiopulmonary

surgery when a heparin-treated blood path is desired.

The Research Medical Venous Return Cannulae are intended for cannula drainage superior and inferior vena cave during extracorporeal circulation for a duration ≤ 6 hours. Venous Cannulae in sizes 6 Fr. to 18 Fr. can be used in pediatric patient populations.

NOTE: The Research Medical 40 Fr. and 46 Fr. Venous Return Cannulae are also intended for use in single cannula return of the right atrium.

The Research Medical Duraflo Heparin Treated Venous Return Cannulae are intended for cannula drainage superior and inferior vena cave during extracorporeal circulation for a duration ≤ 6 hours. Venous Cannulae in sizes 6 Fr. to 18 Fr. can be used in pediatric patient populations.

NOTE: The Research Medical 40 Fr. and 46 Fr. Venous Return Cannulae are also intended for use in single cannula return of the right atrium. Extracorporeal circuit components with a Duraflo Treatment are indicated for use in cardiopulmonary surgery when a heparin-treated blood path is desired.

The Research Medical FEM-FLEX Femoral Access Cannulae are intended for use in situations which require rapid femoral venous and arterial access for short term cardiopulmonary bypass. Venous and arterial access is left to the discretion of the physician for a duration ≤ 6 hours. Femoral Cannulae in sizes 6 Fr. to 14 Fr. can be used in pediatric patient populations.

The Research Medical Duraflo Heparin Treated FEM-FLEX Femoral Access Cannulae are intended for use in situations which require rapid femoral venous and arterial access for short term cardiopulmonary bypass. Venous and arterial access is left to the discretion of the physician for a duration ≤ 6 hours. Femoral Cannulae in sizes 6 Fr. to 14 Fr. can be used in pediatric patient populations. Extracorporeal circuit components with a Duraflo Treatment are indicated for use in cardiopulmonary surgery when a heparin-treated blood path is desired.

Comparative Analysis:	The only difference between the subject catheters and the predicate Research Medical catheters is the subject catheters are smaller in diameter and length. Aside from the smaller sizes, there is no difference between the ERMI Pediatric Venous Return Cannulae and the predicate devices.
Functional/Safety Testing:	The ERMI Pediatric Venous Return Cannulae have successfully undergone functional and biocompatibility testing.
Conclusion:	The ERMI Pediatric Venous Return Cannulae are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2 2004

Edwards Lifesciences LLC
c/o Mr. Jason Smith
Senior Regulatory Affairs Specialist
One Edwards Way
Irvine, CA 92614

Re: K033464
Duraflo® coated and uncoated Venous Return, Dual Drainage Venous Return, and FEM-FLEX Femoral Access Cannulae
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, and Tubing
Regulatory Class: Class II (two)
Product Code: DWF
Dated: May 25, 2004
Received: May 26, 2004

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Lechner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033464

Device Name: Research Medical Venous Return, Dual Drainage Venous Return, Duraflo Heparin Treated Venous Return and FEM-FLEX Femoral Access Cannulae

Indications For Use:

1. The Research Medical Dual Drainage Venous Return Cannulae is indicated for venous cannulation so that extracorporeal circulation of venous blood to a heart-lung machine may be achieved for a duration ≤ 6 hours. Venous Cannulae in sizes 6 Fr. to 18 Fr. can be used in pediatric patient populations.

2. The Research Medical Duraflo Heparin Treated Dual Drainage Venous Return Cannulae is indicated for venous cannulation so that extracorporeal circulation of venous blood to a heart-lung machine may be achieved for a duration ≤ 6 hours. Venous Cannulae in sizes 6 Fr. to 18 Fr. can be used in pediatric patient populations. Extracorporeal circuit components with a Duraflo Treatment are indicated for use in cardiopulmonary surgery when a heparin-treated blood path is desired.

3. The Research Medical Venous Return Cannulae are intended for cannula drainage superior and inferior vena cave during extracorporeal circulation for a duration ≤ 6 hours. Venous Cannulae in sizes 6 Fr. to 18 Fr. can be used in pediatric patient populations.

   NOTE: The Research Medical 40 Fr. and 46 Fr. Venous Return Cannulae are also intended for use in single cannula return of the right atrium.

4. The Research Medical Duraflo Heparin Treated Venous Return Cannulae are intended for cannula drainage superior and inferior vena cave during extracorporeal circulation for a duration ≤ 6 hours. Venous Cannulae in sizes 6 Fr. to 18 Fr. can be used in pediatric patient populations.

   NOTE: The Research Medical 40 Fr. and 46 Fr. Venous Return Cannulae are also intended for use in single cannula return of the right atrium. Extracorporeal circuit components with a Duraflo Treatment are indicated for use in cardiopulmonary surgery when a heparin-treated blood path is desired.

5. The Research Medical FEM-FLEX Femoral Access Cannulae are intended for use in situations which require rapid femoral venous and arterial access for short term cardiopulmonary bypass. Venous and arterial access is left to the discretion of the physician for a duration ≤ 6 hours. Femoral Cannulae in sizes 6 Fr. to 14 Fr. can be used in pediatric patient populations.

6. The Research Medical Duraflo Heparin Treated FEM-FLEX Femoral Access Cannulae are intended for use in situations which require rapid femoral venous and arterial access for short term cardiopulmonary bypass. Venous and arterial access is left to the discretion of the physician for a duration ≤ 6 hours. Femoral Cannulae in sizes 6 Fr. to 14 Fr. can be used in pediatric patient populations. Extracorporeal circuit components with a Duraflo Treatment are indicated for use in cardiopulmonary surgery when a heparin-treated blood path is desired.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmel

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033464